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Development of Standards and Guidelines for Healthcare Surge during Emergencies

Population Rights

NOTE: This document was developed with input from a broad group of stakeholders representing constituent organizations with diverse perspectives and technical expertise. The purpose of eliciting a wide range of input was to ensure the information contained in this document was as comprehensive and as sound as possible.

Although the individuals referenced and the organizations they represent have provided many constructive comments, information and suggestions, they were neither asked nor did they agree to endorse the conclusions or recommendations represented here or in subsequent iterations.

Guidelines Regarding the Transition from Patient-Based to Population-Based Outcomes

Introduction

When a physician graduates from medical school, he / she swears to an oath that embodies the ethics and ideals of Hippocrates, the acknowledged father of modern medicine. Translated from the traditional Greek version, the Hippocratic Oath emphatically states that a physician should "Above all, do no harm" to the patients he / she serves. An excerpt from this oath reads, "I will remember that I remain a member of society, with special obligations to all my fellow human beings." In the current state of medicine, each licensed provider of care has an overarching obligation to treat every individual patient to the best of his or her abilities.

During mass casualty events such as epidemics, terrorist attacks and natural and other disasters that result in large numbers of victims, the demand for medical care may exceed available resources to deliver that care. Surge capacity planning for such resource poor environments must therefore consider a departure from the individual patient-based outcomes that physicians have been long conditioned to uphold in favor of an approach that saves the most lives. In other words, 'clinicians will need to balance the obligation to save the greatest possible number of lives against that of the obligation to care for each single patient.'[1] To the fullest extent possible, this migration from provider's obligation from individual responsibility to population outcome should adhere to the long-standing principles of ethical practice.

Much planning has been undertaken at the federal, state and local levels to enhance surge capacity in response to a large-scale emergency resulting in mass casualties. In August of 2004, the Agency for Healthcare Research and Quality (AHRQ) convened a panel of experts drawn from the fields of bioethics, emergency medicine, disaster management, health administration, law and public health. The deliberations of this panel led to a report, *Altered Standards of Care in Mass Casualty Events*, which outlines a number of important issues and policy recommendations. Two years later, in March of 2006, the New York State Task Force on Life and the Law, at the request of the New York State Department of Health, convened a workgroup to consider clinical and ethical issues in the allocation of mechanical ventilators in an influenza pandemic. The Population Rights work group has adopted a great deal of the thought leadership put forward from both the AHRQ and the New York State guidelines, which were proposed as a draft for public comment March 15, 2007.

The guidelines that follow are divided into four sections.

I. Surge-Related Ethical Principles
II. Caring for Populations with Special Needs
III. Tools to Promote Population-Based Outcomes
IV. Allocation of Scarce Resources, Ventilator-Specific

I. Surge-Related Ethical Principles

[1] NYS Workgroup on Ventilator Allocation in an Influenza Pandemic, NYS DOH / NYS Task Force on Life & the Law. *Allocation of Ventilators in an Influenza Pandemic: Planning Document - Draft for Public Comment.* New York, 15 March 2007

The following principles have been adapted from the Public Health Leadership Society's *Principles of the Ethical Practice of Public Health.*[2]

Principle #1: The local health officer has an ethical obligation to utilize all readily accessible information in a responsible way and in a timely manner in making a determination that a healthcare surge situation exists. The health and medical aspects of system response to a healthcare surge should be coordinated and informed by consideration of ethics.

It is essential that the communication regarding a healthcare surge is accurate and uniform throughout the area affected by the healthcare surge. The following principle combines the thought leadership behind the Public Health Leadership Society's *Principles of the Ethical Practice of Public Health* and AHRQ's *Altered Standards of Care in Mass Casualty Events.*[3]

Principle #2: To the fullest extent possible under the circumstances of a healthcare surge, local health officers and those working under their direction and authority should provide those in the community with accurate information pertaining to the nature of the healthcare surge and the responses to it with reasonable frequency.

To further ensure adherence to this principle, the following points should be kept in mind:

- Public understanding and acceptance of plans are essential to success
- Messages should be as consistent and timely as possible at all stages
- Official health and medical care messages should be delivered through public media by the local physician health officer (or other local physician (e.g., hospital or medical group chief of staff) whom the public perceives to have knowledge of the event and the area), the California state health officer, a representative of the Centers for Disease Control and Prevention, or the Surgeon General depending on the level of communication necessary.
- Spokespersons at all levels (local, State, regional, Federal) should coordinate their messages
- Modes of communication should be tailored to the type of information to be communicated, the target audience for which it is intended, and the operating condition of media outlets, which may be directly affected. Attention to the need to use languages other than English and the use of alternative communication channels outside of usual media outlets are examples of specific concerns. Also, specificity and details within messages would vary by target population (affected area vs. neighboring area vs. the rest of the state).

While the first two principles above speak to the declaration of surge and the communication that must result, the next principles address the important issues that healthcare facilities and workers must face and the difficult decisions required of them. The next principle is adapted from AHRQ's *Altered Standards of Care in Mass Casualty Events*.[3]

Principle #3: In planning for a healthcare surge, healthcare personnel should aim to maintain functionality of the healthcare system and to deliver a quality of care that is optimal under current circumstances. Those persons involved in formulating and implementing the response to a healthcare surge should pursue the goal of preserving as many lives as possible. In pursuit of this goal, those persons should strive, to the fullest extent possible, to respect individual rights and community norms, including but not limited to the following circumstances:

- In establishing and operationalizing an adequate framework for the delivery of care
- In determining the basis on which scarce resources will be allocated

[2] Principles of the Ethical Practice of Public Health, Version 2.2 © 2002 Public Health Leadership Society

[3] Altered Standards of Care in Mass Casualty Events. Prepared by Health Systems Research Inc. under Contract No. 290-04-0010. AHRQ Publication No. 05-0043. Rockville, MD: Agency for Healthcare Research and Quality. April 2005.

The goal of saving as many lives as possible is thus infused with an aim to respect the individual rights of the patient wherever and whenever possible. While apparently contradictory, it describes the ethical challenge of providing care during a healthcare surge. At a time when resources are scarce and time is compromised, reasonable exercise of clinical judgment must still come into play when making decisions.

While the ethical challenge of principle #3 rests on the shoulders of the 'people on the ground' during a healthcare surge, principle #4 emphasizes the responsibility of the healthcare community as a whole.

Principle #4: Reasonable accommodations should be made for the personal needs and commitments of those healthcare and other personnel responding to the healthcare surge.
Note: language from the Personnel workgroup will be used in this section to provide more specificity.

II. Caring for Populations with Special Needs

Caring for populations with special needs during a healthcare surge embodies controversial and sensitive issues. Community based organizations must be involved in the planning, response, and recovery of healthcare surge event.

In disaster preparedness, the term "vulnerable" or "special needs" people or populations are used to define groups whose needs are not fully addressed by traditional service providers. It also includes groups that cannot comfortably or safely access and use the standard resources offered in disaster preparedness, response and recovery. This includes, but it not limited to, those who are physically and/or mentally disabled (blind, cognitive disorders, mobility limitations), limited or non-English speaking, geographically or culturally isolated, medically or chemically dependent, homeless, Deaf and hard-of-hearing, frail elderly and children.[4]

When planning for a healthcare surge, it is essential that the special needs of several groups within the general population are taken into consideration. These needs may vary, including but not limited to:

- Communicating disaster information in a variety of languages. Having translators available at intake centers
- Providing mental health assessment resources within the healthcare setting
- Delivering emergency food, health care and counselling
- Providing alternative housing for displaced persons
- Providing shelter facilities with appropriate support services
- Providing for alternate means of decontamination for babies and other non-ambulatory persons
- Ensuring vulnerable persons have services for an effective recovery
- Addressing long term recovery issues

In *Meeting the Needs of Vulnerable People in Times of Disasters: A Guide for Emergency Managers,* the California Governor's Office of Emergency Services suggests that involving organizations and services designed to serve groups with special needs might be an appropriate approach.

'Community-based organizations (CBOs) provide a direct link to the local communities and the vulnerable people that CBOs serve.' Emergency management could be improved with the involvement of CBOs because they:

- Have pre-established networks for delivering services
- Have access to communities the government may not be able to reach

[4] Meeting the Needs of Vulnerable People in Times of Disaster: A Guide for Emergency Managers. California Governor's Office of Emergency Services, 2000

- Understand the needs of their vulnerable clients
- Have the ability to respond quickly to local issues
- Enhance the cultural competency of government to meet needs
- Have the ability to provide information to people in their own language

Needless to say, a victim's underlying medical condition may affect their survivability, and therefore may be considered negatively in the criteria used to allocate scarce resources. For example, resources may be diverted away from an adult and given to a child due to the child's greater life expectancy. However, Community-based organizations bring expertise in delivering services to accommodate people and communities with language, cultural, and accessibility needs. The most effective way to provide the 'greatest good to the greatest number' of individuals with special needs is to have CBOs active in the response and recovery plan.

III. Tools to Promote Population-Based Outcomes

Healthcare providers should be able to fully adhere to the standards established by existing laws and the core values and principles of public health law and ethics during a healthcare surge. Such individuals should depart from those core values and principles only when the nature and extent of the healthcare surge precludes full adherence to them.

However, it is inevitable that during a healthcare surge, individuals providing healthcare services in licensed healthcare facilities and alternate care sites will be unable to fully adhere to statutes, regulations and professional standards of practice relating to patient rights and professional ethics, including obtaining informed consent; honoring advance healthcare directives; communicating with healthcare agents, surrogates and next of kin; providing services to special needs populations; withdrawing care; and disposing of human remains. As such, it is anticipated that the legal requirements concerning such rules will be waived by government authorities. The tools included below aim to alleviate, to the extent possible, concern over the liability associated with making such difficult decisions.

Tool #1: Standards Related to Informed Consent during a Healthcare Surge

A healthcare provider is not obligated to obtain informed consent, as that term is defined by applicable facility policy and/or professional standards of practice, before rendering a healthcare service or procedure during a healthcare surge, when any one or more of the following circumstances are present:

1. The patient is unconscious, the healthcare provider believes that the service or procedure should be undertaken immediately, and the healthcare provider believes the patient's legal representative for healthcare decisions is not immediately available. (See Tool #3 relating to communication with legal representatives for healthcare decisions.)

2. The medical service or procedure is undertaken without the consent of the patient because the healthcare provider believes that the service or procedure should be undertaken immediately and there is insufficient time to fully inform the patient.

3. A medical service or procedure is performed on a legally incapable of giving consent, and the healthcare provider believes that the procedure should be undertaken immediately and there is insufficient time to obtain the information consent of the person authorized to give such consent for the patient.

Healthcare providers are required to document the presence or absences of these circumstances if and only if time, circumstances and professional judgment permit such documentation.

Tool #2: Standards Related to Advanced Healthcare Directives during a Healthcare Surge

A healthcare provider is obligated to inquire about, read or adhere to an Advanced Healthcare Directive, as that term is defined under applicable facility policy, state law and/or professional standards of practice, before rendering a healthcare service or procedure during a healthcare surge, if and only if all of the following circumstances are present:

1. The healthcare provider is aware of the terms of the Advanced Healthcare Directive.

2. The healthcare provider believes that accommodating the terms of the Healthcare Directive will not require time, staff or resources that would otherwise be utilized in the care of other individuals.

Healthcare providers are required to document the presence or absences of these circumstances if and only if time, circumstances and professional judgment permit such documentation.

Tool #3: Standards Related to Communicating with Legal Representatives for Healthcare Decisions during a Healthcare Surge

A healthcare provider is not obligated to locate or obtain informed or other consent from a patient's legal representative for healthcare decisions (including but not limited to the parent or guardian of a minor child, a conservator, an agent for health care decisions, a surrogate or next of kin), before rendering a healthcare service or procedure during a healthcare surge, unless the following circumstance is present:

1. The healthcare provider knows that the legal representative for healthcare decisions is immediately available to the healthcare provider. "Immediately available" means the representative is physically present next to the patient.

Healthcare providers are required to document the presence or absences of these circumstances if and only if time, circumstances and professional judgment permit such documentation.

Tool #4: Standards Related to Providing Services to Individuals with Special Needs during a Healthcare Surge

Individuals with special needs have the same rights to health care services as individuals who do not have special needs during a healthcare surge. Therefore, the decision by a health care provider as to whether an individual should be provided with health care services (including but not limited to health care services and procedures, pharmaceuticals and accommodations), should be based on the acceptable criteria for resource allocation as set forth in the 'Scarce Resource Allocation' section below and not on whether the individual meets the definition of an individual with special needs.

Tool #5: Standards Related to Allocation and Withdrawal of Care:

Decisions as to who should receive care and when care should be withdrawn and/or discontinued, should be based on the principles set forth in the 'Scarce Resources Allocation' section (Section V) below.

1. A healthcare provider may determine that an individual will not receive care, or that care currently being provided to an individual will be discontinued or withdrawn, based on the criteria identified in Section V below. Examples of care that may be denied or discontinued or withdrawn in order to allocate limited resources in accordance with the criteria identified in Section V, include but are not limited to ventilator support, antibiotics, hydration and life-sustaining nutritional support, ICU and other facility beds and supplies, and blood.

2. When a decision is made to deny or discontinue or withdraw care, palliative care should be offered to the affected individual whenever such palliative care is reasonably available. Palliative care includes but is not limited to sedation and supplements to breathing.

3. When a decision is made to deny or discontinue or withdraw care, the healthcare provider should, when time and circumstances reasonably permit, clearly document the rationale for the decision on a document that will remain in the facility.

Tool #6: Standards Related to Disposal of Human Remains during a Healthcare Surge

The manner and process for disposing of human remains during a Health Care Surge will be based on directives from state and local health care authorities and not on the requests of the patient in an Advanced Health Care Directive or requests by the patient's legal representative for health care decisions.

The tools above aim to release healthcare facilities and providers of certain legal obligations that could not appropriately be met during a healthcare surge. These tools are meant to alleviate legal liability but not to dismiss each caregiver's ethical obligations to individuals wherever possible.

IV. Scarce Resource Allocation

The provision of care in the setting of a large-scale disaster must be a sliding scale of care appropriate to the resource demands of the event. Healthcare facilities and providers managing a large excess of demand over supply of services during a healthcare surge will likely need to allocate resources in ways that are unique to the surge event.

The following practice guidelines have been adapted from the American Medical Association's *Ethical Considerations in the Allocation of Organs and Other Scarce Medical Resources among Patients*. Their purpose is to give ethical guidance to healthcare facilities and providers for both the acceptable and the inappropriate criteria for making resource allocation decisions during a healthcare surge event.

Acceptable Criteria for Resource Allocation among Patients

Likelihood of Survival
During a healthcare surge, priority of resource allocation and treatment should be given to patients with a greater likelihood of survival. This is an essential component in maximizing best outcomes and saving the most number of lives.

Change in Quality of Life
The benefit of the population of patients during a healthcare surge will be maximized if treatment is provided to patients who will have the greatest improvement in quality of life. Quality of life can be defined by comparing functional status with treatment to functional status without treatment.

Duration of Benefit
The length of time each patient will benefit from treatment is an appropriate consideration in allocating scarce medical resources during a healthcare surge. By giving higher priority to patients who will benefit longer than other patients, scarce resources will be directed to patients who will benefit the most.

Urgency of Need
Prioritizing patients according to how long they can survive without treatment can often maximize the number of lives saved. However, urgency of need should only be applied to patients who

have presented themselves during a healthcare surge, not to hypothetical patients that a healthcare facility or provider forecasts receiving. Resources should not be denied to patients because other patients with more urgent need may soon present.

Amount of Resources Required

In a situation where resources are limited, it will be necessary to treat patients who will need less of a scarce resource rather than patients expected to need more. This will maximize the number of patients who will benefit.

Inappropriate Criteria for Resources Allocation among Patients

Ability to Pay

During a healthcare surge, healthcare facilities and providers should not systematically deny needed resources to patients simply due to their lower economic status.

Social Worth

A patients' contribution to society, or his/her social worth, should not be a factor in resource allocation decisions during a healthcare surge. A social worth criterion undermines the focus on the welfare of the patient and prohibits achievement of the overall goal to maximize the best outcome for the greatest number of patients.

Patient Contribution to Disease

This criterion assigns a lower priority to patients whose past behaviors are believed to have contributed significantly to their present need for scarce resources. Examples include heart transplant candidates whose high fat diets may have contributed to their condition. Using judgments about patients' morals to allocate healthcare is inappropriate and inconsistent.

Past Use of Resources

It may be argued that during a healthcare surge, patients who have had considerable access to a scarce medical resources in the past should be given a lower priority than equally needy patients who have, up to the time of the surge, received relatively less of that resource. Because past use is irrelevant to present need, it should not factor into allocation decisions.

Special Case - Allocation of Ventilators for Pandemic Flu Scenario

The following is adopted from a draft of the New York State Task Force on Life and the Law, March 2007.

Duty to Care

The ethical rationing system for allocation of ventilators must support the fundamental obligation of health care professionals to care for patients. While ventilator allocation decisions may involve the choice between life and death, to the fullest extent possible, physicians must strive to ensure the survival of each individual patient. Guidelines must stress the provision of care that is possible when ventilation is not. Patients who do not receive mechanical ventilation must not be disregarded entirely. These patients must receive the next best care under the circumstances, whether it be other forms of curative treatment or palliative care.

Duty to Steward Resources

During a healthcare surge, clinicians will need to balance the obligation to save the greatest possible number of lives against their long standing responsibilities to care for each single patient. Government and healthcare providers must embrace this obligation to devise a rationing system and be prepared for the ethical tension that will result.

Duty to Plan

Planning is not a recommendation but an obligation. The absence of guidelines would leave important allocation decisions to be made by exhausted providers which would result in a failure of responsibility toward both patients and providers.

Distributive Justice

The same allocation guidelines should be used across the state. These allocation guidelines must not vary from private to public sector. They need to remain consistent throughout the community at hand. Also, the allocation of ventilators from state and federal stockpiles must take into account the ratio of local populations to available resources, designating appropriate resources for the most vulnerable who are most likely to suffer the greatest impact in any disaster.

Transparency

Any just system of allocating ventilators will require robust efforts to promote transparency. Proposed guidelines should be publicized and translated into different languages as necessary. However, disaster planning must not serve as a covert means to resolve the long-standing problems of health care. [5]

Guidelines Related to the Withdrawal / Restriction of Ventilator Support

During a healthcare surge, as the demand for mechanical ventilation increases, the supply of each facility's ventilators will naturally decrease. To speak to this dilemma, in *Concept of Operations for Triage of Mechanical Ventilation in an Epidemic*, Hick, et al. published a number of criteria to be used with regards to the withdrawal or restriction of ventilator support. Hick et al. recommend that criteria for ventilator allocation should be implemented in a tiered fashion to provide a scalable framework for restriction. Withholding and withdrawing ventilatory support are ethically indistinct, and are thus listed together in the criteria.

First-Tier Criteria

The first tier would eliminate access to ventilators for patients with the highest probability of mortality.

Second-Tier Criteria

If resources continue to decrease during a healthcare surge, the second tier would deny ventilatory support to patients with respiratory failure as well as a high use of additional resources. This tier includes patients who have a pre-existing illness with a poor prognosis.

Third-Tier Criteria

When resources continue to decrease, a third tier of criteria would need to be implemented. This criteria lacks the specificity of the first two, as Hick et al. suggest that this may need to be a real time decision on criteria to be used.

Note: Hick et al. also proposed the very controversial idea that any patient 'who might be stable, or even improving, but whose objective assessment indicates a worse prognosis than other patients who require the same resource'[6] should be extubated to free up the ventilator for the new patient with the better prognosis. The New York State Task Force on Life and the Law disagreed with such a view, expressing significant reservations due to the fact that 'patients require a sufficient trail on the ventilator in order to determine it benefit,' and that 'if ventilator use is primarily determined by the health of other potential users of the ventilator, clinicians must abandon their obligation to advocate for individual patients.'[5]

Allocation of Ventilators - Sample Clinical Evaluation

Mechanical ventilators should be allocated to patients during a pandemic based on each patient's clinical evaluation. This clinical evaluation system could be based on a clinical protocol such as OHPIP (Ontario Health Plan for an Influenza Pandemic) protocol and on each patient's SOFA score (Sepsis-related Organ Failure Assessment).

[5] NYS Workgroup on Ventilator Allocation in an Influenza Pandemic, NYS DOH / NYS Task Force on Life & the Law. *Allocation of Ventilators in an Influenza Pandemic: Planning Document - Draft for Public Comment.* New York, 15 March 2007

The OHPIP protocol utilizes the SOFA score to add points to each patient based on objective measures of function in six key organs and systems: lungs, liver, brain, kidneys, blood clotting and blood pressure. A perfect SOFA score, indicating normal function in all six categories, is 0; the worst possible score is 24 and indicates life-threatening abnormalities in all six systems. SOFA scale included directly below.

Sequential Organ Failure Assessment (SOFA) score SOFA Scale

Variable	0	1	2	3	4
PaO2/FiO2 mmHg	>400	≤ 400	≤ 300	≤ 200	≤ 100
Platelets, x 103/µL (x 106/L)	> 150 (>150)	≤ 150 (≤ 150)	≤ 100 (≤ 100)	≤50 (≤50)	≤ 20 (≤ 20)
Bilirubin, mg/dL (µmol/L)	<1.2 (<20)	1.2-1.9 (20 – 32)	2.0-5.9 (33 – 100)	6.0-11.9 (101 – 203)	>12 (> 203)
Hypotension	None	MABP < 70 mmHg	Dop ≤ 5	Dop > 5, Epi ≤ 0.1, Norepi ≤ 0.1	Dop > 15, Epi > 0.1, Norepi >0.1
Glasgow Coma Score	15	13 - 14	10 - 12	6 - 9	<6
Creatinine, mg/dL (µmol/L)	< 1.2 (<106)	1.2-1.9 (106 – 168)	2.0-3.4 (169 - 300)	3.5–4.9 (301 – 433)	>5 (> 434)

Dopamine [Dop], epinephrine [Epi], norepinephrine [Norepi] doses in ug/kg/min
SI units in brackets
Adapted from: Ferreira FI, Bota DP, Bross A, Melot C, Vincent JL. Serial evaluation of the SOFA score to predict outcome in critically ill patients. JAMA 2001; 286(14): 1754-1758. Explanation of variables: PaO2/FiO2 indicates the level of oxygen in the patient's blood. Platelets are a critical component of blood clotting. Bilirubin is measured by a blood test and indicates liver function. Hypotension indicates low blood pressure; scores of 2, 3, and 4 indicate that blood pressure must be maintained by the use of powerful medications that require ICU monitoring, including dopamine, epinephrine, and norepinephrine. The Glasgow coma score is a standardized measure that indicates neurologic function; low score indicates poorer function. Creatinine is measured by a blood test and indicates kidney function.

Patients on ventilators pre-event will also be assessed to see whether they meet criteria for continued use. When a ventilator becomes available and many potential patients are waiting, clinicians may choose the patient with pulmonary failure who has the best chance of survival with ventilatory support, based on objective clinical criteria.

Time Trials

The New York State Task Force on Life and the Law recommends that continued use of ventilators will be reviewed and reassessed at intervals of 48 and 120 hours. Patients who continue to meet criteria for benefit or improvement would continue until the next assessment, while those who no longer meet these criteria would lose access to mechanical ventilation.

Exclusion Criteria

The New York State Task Force on Life and the Law recommends that clinicians assess patients for exclusion criteria both to determine the appropriateness of the initiation and continuation of ventilator use. Exclusion criteria should focus primarily on current organ function, rather than on specific disease entities. A revised set of exclusion criteria is presented below.

Exclusion Criteria for Ventilator Access*

- Cardiac arrest: unwitnessed arrest, recurrent arrest, arrest unresponsive to standard measures; Trauma-related arrest
- Metastatic malignancy with poor prognosis
- Severe burn: body surface area >40%, severe inhalation injury
- End-stage organ failure:
    - o Cardiac: NY Heart Association class III or IV
    - o Pulmonary: severe chronic lung disease with FEV1** < 25%
    - o Hepatic: MELD*** score > 20
    - o Renal: dialysis dependent
    - o Neurologic: severe, irreversible neurologic event/condition with high expected mortality

*Adapted from OHPIP guidelines
** Forced Expiratory Volume in 1 second, a measure of lung function
*** Model of end stage liver disease

These criteria must be seen as guidelines, not standards. 'More important than the specifics of any tool (which will require modification based on the event) is the establishment of a process for making decisions to limit care so that in a time of crisis, a mechanism is in place to apply as much science as possible to these decisions and the persons involved are prepared for their roles.'[6]

[6] Hick, J.L., et al; *Concept of Operations for Triage of Mechanical Ventilation in an Epidemic*; *Acad Emerg Med* 2006; 13:223-9